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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
TUNG, J	
ART UNIT	**PAPER NUMBER**
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/956,349	Applicant(s) Saunders
	Examiner Joyce Tung	Group Art Unit 1634

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-20 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1-20 of copending Application No. 08/738,552. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented

Claim Rejections - 35 USC § 112

3. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. These claims are confusing because of the language "surface" in claims 1, 2, 5 and 19. It cannot be determined what is encompassed.

b. Claims 5-8, 10-18 are confusing because of the language "treating the surface with a DNA-inactivating agent". It is not clear what the purpose is in treating the surface with DNA-inactivating agent.

c. Claim 1 is confusing because a connection language such as "comprising" after "a cell population" on the first line is missing.

d. Claims 19 and 20 are confusing because of the language "the material" in claim 19 which has no antecedent basis.

e. Claims 18 is confusing because of the language "instruction". It cannot be determined what is encompassed.

f. Claims 19-20 are confusing because there are several typographical errors, for example, "determing" and "solublilized".

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ornstein (4,545,831) in view of Emmert-Buck et al. (Science 1996, Vol. 274 (8), pg. 998-1001).

Claim 1 is drawn to a method to separate a rare cell in a cell population. The method involves applying cells from the cell population to a surface, determine the location of the cell on the surface and covering the cell with a solidifiable material, illuminating the cover to form a solid plug, removing the plug and then the cell is separated from the population.

Claim 3 recites a further limitation to claim 1 in which the solidifiable material is from bisphenol A type epoxy acrylate oligomer, methacrylate, urethane acrylate oligomer and so on.

Claim 9 recites further limitation to claim 1 in which the cell population is a tissue section.

Ornstein discloses a process to transfer a thin tissue in which the tissue is affixed to a surface which is layer 14 (see fig. 1) on a substrate and the tissue is covered by a layer 18 supported by a microscope slide 16 (see fig. 3a). The layer 18 is formed by photo polymerization (see column 4, line 1). The layer 14 and substrate can be removed by immersing the laminate 20 in a solvent solution (see column 4, line 49-54). The tissue affixed to the microscope slide by layer 18 is for further processing (see Abstract). The photopolymerizable material contains epoxyacrylate oligomer with many bisphenol A and urethane acrylate oligomer (see column 5, line 5-10)

Orntsein does not disclose a process to separate a cell from a cell population.

Emmert-buck et al. disclose a method to capture a cell population in which a tissue is placed on a glass histopathology slide and covered by a transparent thermoplastic film. A laser pulse specifically activates the film under direct microscopic visualization (see pg. 998, Abstract).

One having ordinary skill in the art would have been motivated to modify the method of Orntein by illuminating a covered cell population under microscopic vision and specifically focusing the cell of interest as taught by Emmert-buck et al. because if a very thin tissue is under microscopic vision, each individual cell can be visualized and selected. This was well known in the art. Additionally, the layer 18 in the method of Ornstein can be used under a microscope (see

column 5, line 29-30). Therefore, a skilled artisan would have used a microscope to select a cell in which a light source selectively focuses on a cell of interest covered with a photopolymerizable material under a microscope to form a solid cover attaching the cell. It would have been prima facie obvious to carry out the method as claimed.

6. Claims 2, 5-8, 10 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ornstein (4,545,831) in view of Emmert-Buck et al. (Science 1996, Vol. 274 (8), pg. 998-1001) and Sekizawa et al. (Neurology 1996, Vol. 46, pg. 1350-1353).

Claims 2, 5-8, 10 and 13-18 are drawn to a method and kit to analyze DNA of a rare cell in a cell population. The method involves the steps described in claim 1 for separating the rare cell from the cell population and an additional step of analyzing DNA via the polymerase chain reaction or ligase chain reaction. The rare cell is a fetal cell or malignant cell or a nucleated red blood cell. The reaction is carried out after the rare cell is removed from the surface.

The teachings of Ornstein and Emmer-Buck et al. are stated in paragraph 5. Neither of the references discloses a kit and an amplification reaction to analyze DNA from a rare cell after the rare cell is removed from a surface.

Sekizawa et al. disclose a method to diagnose prenatal Duchenne muscular dystrophy using a nucleated erythrocyte. A single nucleated erythrocyte is fixed on a microscopic slide (see pg. 1351, Method). The genome from a single cell is amplified by polymerase chain reaction (see Abstract).

One having ordinary skill in the art would have been motivated to modify the method of Orntein as described in paragraph 5 and by applying amplification method as taught by Sekizawa et al. because Sekizawa et al. teach using a single nucleated erythrocyte fixed on a glass slide in which DNA is amplified by polymerase chain reaction. A skilled artisan would have also constructed a kit to perform the method because it was conventional in the art to package all ingredients necessary for performing a method. It would have been prima facie obvious to carry out the method as claimed.

7. Claims 4 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ornstein (4,545,831) in view of Emmert-Buck et al. (Science 1996, Vol. 274 (8), pg. 998-1001), Sekizawa et al. (Neurology 1996, Vol. 46, pg. 1350-1353), and Sandner et al. (3,715,293).

Claims 4, and 11-12 recite further limitations to claims 1 and 5 in which a solidifiable material comprises 2,2dimethoxy-2-phenyl acetophenone.

The teachings of Ornstein and Emmert-Buck et al. are stated in paragraph 5 and the teaching of Sekizawa et al. is stated in paragraph 6. None of the references discloses that the solidifiable material comprises 2,2dimethoxy-2-phenyl acetophenone.

Sandner et al. disclose a coating composition comprising photosensitizer 2,2-dimethoxy-2-phenyl acetophenone (see abstract).

One having ordinary skill in the art would have been motivated to use the photosensitizer 2,2-dimethoxy-2-phenyl acetophenone as a solidifiable material because Sandner et al. teach that this composition can be polymerized under radiation (see column 3, lines 1-3). It would have been

prima facie obvious to use 2,2-dimethoxy-2-phenyl acetophenone as the solidifiable material as claimed.

Allowable Subject Matter

8. Claims 19 and 20 are free of the prior art, but are rejected for other reasons.

9. The following is a statement of reasons for the indication of allowable subject matter:

No prior art has been found teaching or suggesting a photodepolymerizable coating used to cover cells, the coating is solidified by heat and then solubilized by illumination and DNA of the cells is exposed and followed by amplification. The closest prior art is the reference of Ornstein and Sekizawa. Neither of the reference teaches a photodepolymerizable coating used to cover cells.

10. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152. The fax number for Art Unit 1807 is (703)305-7401.

Any inquiries of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

March 12, 1998

W. GARY JONES
SUPERVISORY PATENT EXAMINER
AU 1634
3/16/98